

PATENT  
0510-1114

**IN THE U. S. PATENT AND TRADEMARK OFFICE**

In re application of

Jean-Pierre COUGOULIC

Conf. 7167

Application No. 10/540,756

Group 1796

Filed June 24, 2005

Examiner M. Pepitone

MEDICAL OR VETERINARY MATERIAL, METHOD  
FOR THE PRODUCTION AND USE THEREOF

**DECLARATION UNDER RULE 132**

Assistant Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

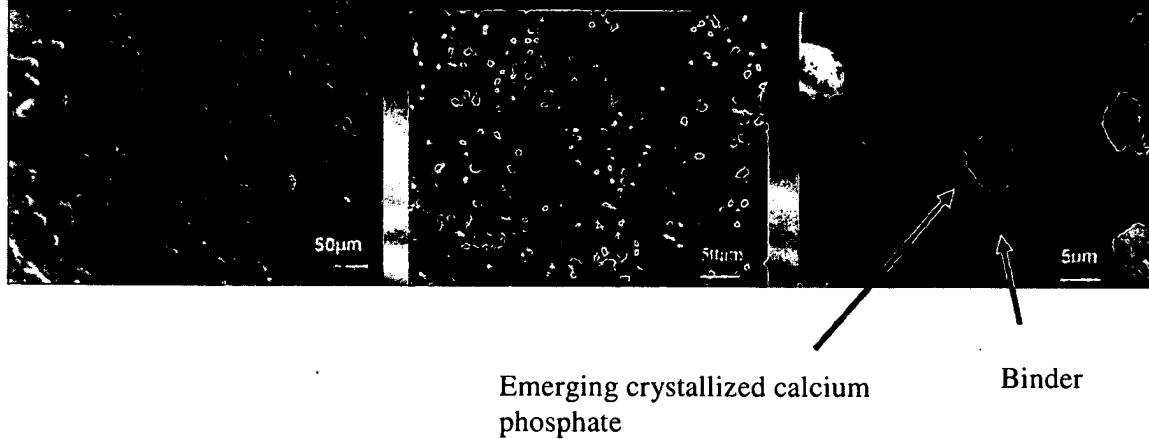
1. I, Jean-Pierre COUGOULIC, the named inventor, am a citizen of France and reside at 7bis avenue du 18 Juin 1940, 44380 Pornichet, France.

2. I am familiar with the above-identified U.S. patent application, its prosecution before the United States Patent and Trademark Office, and the applied references of COUGOULIC (U.S. Patent 5,872,159), ELLINGSEN et al. (U.S. Publication 2002/0111694) and MILLS et al. (U.S. Patent 6,482,584). I am also the inventor of the prior art reference of COUGOULIC, and thus have intimate knowledge of this reference.

3. In order to demonstrate the patentability and unexpected results of the present invention, I am submitting the following observations and results.

The present invention pertains to a material for medical or veterinary usage that is formed from calcium phosphate and polymer biocompatible binder. The surface of this material is provided with emerging crystallized calcium phosphate. The emerging crystallized calcium phosphate can be seen in the photomicrograph reproduced below.

**Microgeometry: it governs the cellular answer.**  
**It is completely different between a molded or manufactured material. Below,SEM of BIOPIK® during surface treatment .**



COUGOULIC fails to disclose or infer a provided with emerging crystallized calcium phosphate. As evidence thereof (which is also set forth in the accompanying declaration), here

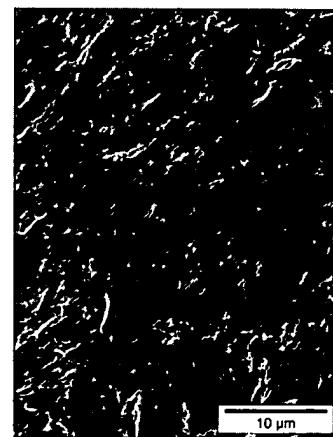
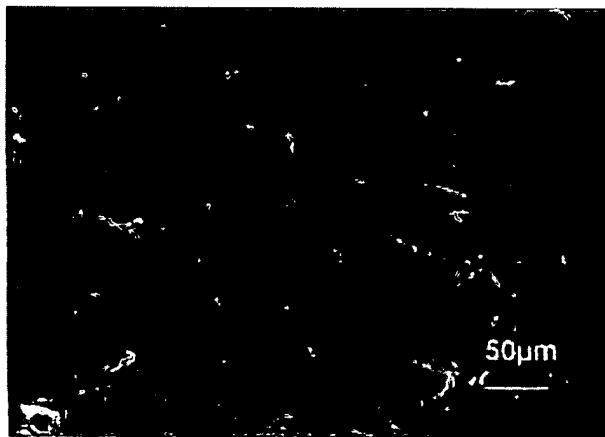
are presented results obtained by Scanning Electron Microscopy of the material with all the claimed ingredients after autoclaving, without and with prior surface treatments.

The corresponding material is here made of the following ingredients :

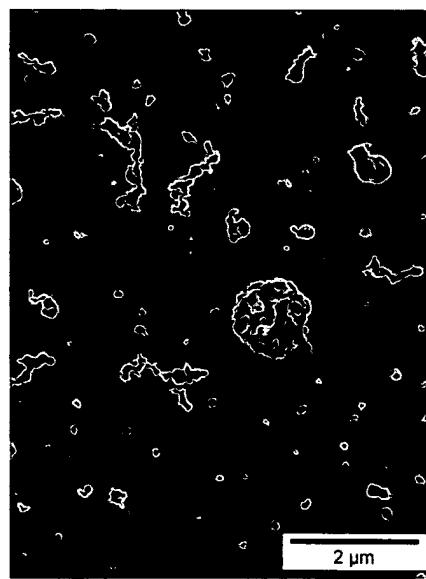
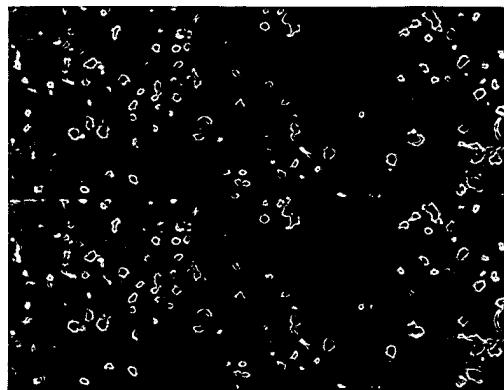
- 80% PEEK
- 10% TiO<sub>2</sub>
- 8% tricalcic phosphate
- 2% calcium hydroxyapatite

The material was formed by injection molding

a/ Material corresponding to Cougoulic prior art, with only sterilization by autoclave (but without prior surface pickling/decontamination treatments):



b/ Material according to the invention, i.e. COUGOULIC with surface pickling/decontamination treatments and then autoclave:



The molded material (a), corresponding to COUGOULIC, is provided with a surface composed of biocompatible binder.

Moreover, the calcium phosphates integrated in the matrix are not in a crystallized state.

***The COUGOULIC material of the prior art, only due to the claimed ingredients, is thus not provided with the emerging crystallized calcium phosphates.***

In contrast, the material (b), according to the present invention, is provided at its surface with the emerging crystallized calcium phosphate.

These photos and analyses obtained by Scanning Electron Microscopy show thus clearly that the emerging crystallized calcium phosphates of the material are not inherently achieved by a composition with all the claimed ingredients.

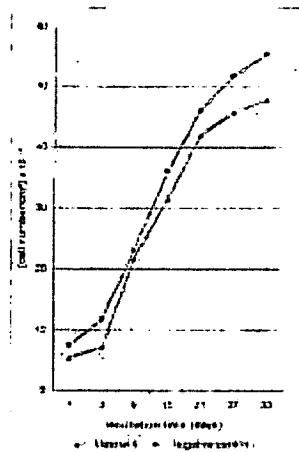
***Only the material according to the present invention is provided with such emerging crystallized calcium phosphates.***

Moreover, the inventor showed that the surface of the material in accordance to the present invention, is interesting in that it confers some particularly efficient integration characteristics to the surrounding tissue, better than the ones of the material not having such emerging crystallized calcium phosphates.

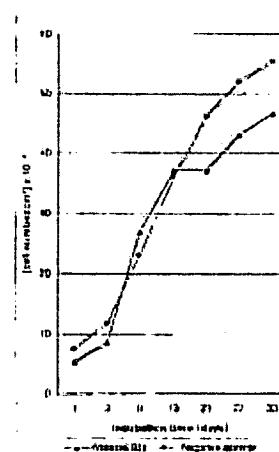
These characteristics are confirmed by the attached LEMI study, with the following products:

- Material B(ii) : Material according to COUGOULIC;
- Material A and B(i) : Material of the invention (these materials differ just due to the type of PEEK used).

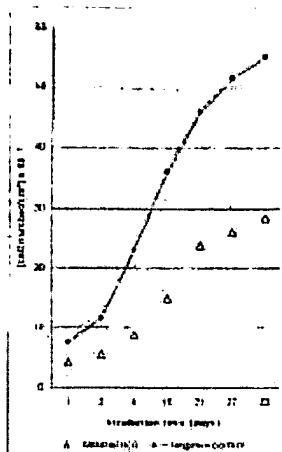
Please see in particular results 4.1.2 - Cell proliferation:



Material A  
Cells culture (human osteoblast) on  
material  
according to the invention (CE  
norms) with  
the surface treatment,  
versus same negative control



Material B(i)  
Cells culture (human osteoblast) on  
material  
according to the invention (US  
norms) with  
the surface treatment,  
versus same negative control



Material B(ii)

Cells culture (human osteoblast) on COUGOULIC material (i.e. without the surface treatment), versus same negative control.

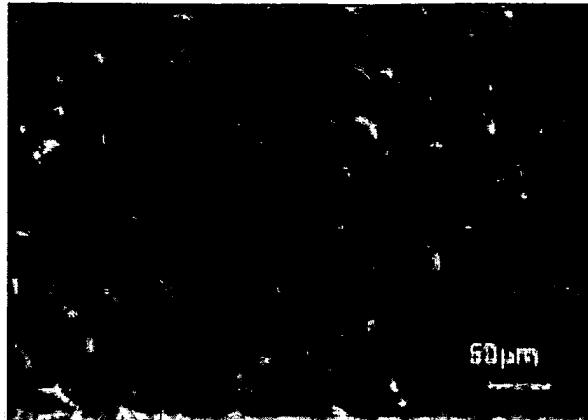
Also, the method of the present invention can include pickling and decontamination processes. At least two points are advantageous to optimize this process:

- the successive steps of the surface pickling and decontamination operations, - the surface pickling and decontamination operations on the molded piecework are made before the sterilization operation by autoclave.

As mentioned above, the material treated only by autoclave does not have any emerging crystallized calcium phosphate.

Moreover, please find below a photo obtained by Scanning Electron Microscopy of the material with all the

claimed ingredients, treated only by surface pickling/decontamination without autoclaving.



These results also show that the material of the invention is different from COUGOULIC, and should be regarded as new and patentable.

Due to these reasons, the activated material according to the present invention should be regarded as new and inventive, compare to COUGOULIC (and also to the other applied art references).

LEMI study report 2004-DQY69-1 is attached to this declaration as further evidence of the patentability of the present invention.

4. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date 2009 02 20

  
Dr. Jean-Pierre COUGOULIC

ATTACHMENT: LEMI study report 2004-DQY69-1